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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,171	01/15/2004	Allyn Hubbard	B1102.70015US01 1143	
23628 7590 12/26/2007 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE			EXAMINER	
			GORDON, BRIAN R	
BOSTON, MA	. 02210-2206		ART UNIT PAPER NUMBER	
			1797	
				-
			MAIL DATE	DELIVERY MODE
			12/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

,		Application No.	Applicant(s)				
Office Action Summary							
		10/760,171	HUBBARD ET AL.				
		Examiner	Art Unit				
		Brian R. Gordon	1797				
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
VVHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAISIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  till apply and will expire SIX (6) MONTHS from  cause the application to become ARANDONE	N. nely filed the mailing date of this communication. D. (35 U.S.C. 8 133)				
Status							
1)🖂	Responsive to communication(s) filed on 11-29	<u>9-07</u> .					
2a) <u></u> □	This action is <b>FINAL</b> . 2b) This action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposit	ion of Claims						
4) 🖂	Claim(s) <u>1-54</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
	5) Claim(s) 1-52 is/are allowed.						
	Claim(s) 53-54 is/are rejected.						
7)	Claim(s) is/are objected to.						
8)□	Claim(s) are subject to restriction and/or	election requirement.					
Applicati	on Papers						
	The specification is objected to by the Examiner						
			- - - - - -				
<i>,</i> —	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachmen	t(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date							
3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application							
Paper No(s)/Mail Date 6) Other:							

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### **DETAILED ACTION**

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# Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrases "arranged to be rotatable", "arranged to support a cell" and "arranged to bind". Does this mean the chip is in a specified location? Is the chip located on a mechanical device that rotates the chip? Does this mean the chip has some other specified structure. As to the latter phrases of arranged to support and bind, does applicant intend to claim the chip reaction sites includes a specified bonding or attracting agent? Or does this refer to the device being a specified location to be exposed to the selected targets?

# Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claim 53 is rejected under 35 U.S.C. 102(e) as being anticipated by Reber et al., US 5,935,785.

Reber et al. disclose a disk shaped device with DNA (cell) binding assays with binding sites arranged either in a circular grid or lattice, or in a spiral grid or lattice on a disk-shaped member. Additionally, the binding assays include machine-readable data to identify the binding sites (column 2, lines 12-16).

5. Claim 53 is rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard Jr. et al., US 6,953,550.

Sheppard Jr. et. al. disclose an integrated, affinity-binding based, analytical apparatus for detecting particulates, particularly cells, suspended in a fluid, preferably a biological fluid. The invention provides a platform for performing an affinity-binding based assay for specifically binding particulates such as cells, preferably microbial cells, especially bacterial cells, and mammalian cells, especially hematopoietic cells, and a detection means for detecting the particulates specifically bound to a defined surface (column 3, lines 15-24).

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Such arrays can be discrete arrays each comprising a different specific binding reagent or can be integrated to comprise a pattern of each of the multiplicity of distinct specific binding reagents. Exemplary patterns include alternating strips, checks, and concentric circles. Similarly, patterns of transparent, specific binding reagent-coated portions and reflective, non-binding portions are provided by the invention. Exemplary patterns include alternating strips, checks, and concentric circles, most preferably comprising a pattern resembling or comprising a "bar code." (column 10, line 66 – column 67, line 9)

## Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takase et al. (EPA 0,417,305 A1).

Takase et al. disclose an apparatus for performing assays substantially as claimed. The apparatus comprises an axially rotatable substrate 101 (chip) having a plurality of radially-arrayed reaction sites 102, 104 means for rotating and controlling the rotation of substrate 101, a fluid dispenser 7 or nozzle 9 for conveying fluid to reaction sites (column 13, lines 53-57), a readout device 11 for reading reactions at reaction sites/marks, means 19 for identifying the reactions sites (figures 1, 2, and 9-11).

Takase et al. disclose the claimed invention except for the presence of 20,000 reaction sites. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide a high number of reaction sites to increase

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sites (column 13, lines 53-57), a readout device 11 for reading reactions at reaction sites/marks, means 19 for identifying the reactions sites (figures 1, 2, and 9-11).

Takase et al. disclose the claimed invention except for the presence of 20,000 reaction sites. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide a high number of reaction sites to increase the throughput and number of testing which may be conducted simultaneously thereby making the process more efficient. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

7. Claims 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber et al., US 5,935,785.

Reber et al. disclose the claimed invention except for the presence of 20,000 reaction sites. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide a high number of reaction sites to increase the throughput and number of testing which may be conducted simultaneously thereby making the process more efficient.

#### Allowable Subject Matter

8. Claims 1-54 are allowed.

#### Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gamble et al. discloses a rotatable substrate.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/ Primary Examiner Art Unit 1797

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